

REMARKS/ARGUMENTS

Claims 23-33 and 125-135 are pending. By this Amendment, claim 23 is amended, and new claims 127-135 are presented. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

At the outset, Applicants appreciate the courtesies extended by Examiners Bennett and Odland during a personal interview conducted on December 10, 2003. The substance of the personal interview is discussed below.

Applicants appreciate that the previous rejection of claims 23-33 has been withdrawn.

Claims 23-28 and 125 were rejected under 35 U.S.C. §102(b)/103(a) over Venegas.

Venegas is directed to a face mask for use with intermittent positive pressure breathing (IPPB) apparatuses. See column 1, lines 8-10. IPPB is a method for intermittently delivering breathable gas to the patient under positive pressure, during inspiration. See the attached textbook excerpts from Tobin et al. (Chapter 9 – Pressure Support Ventilation (Laurent Brochard), p. 245) and McPherson et al. (p. 252), each of which describes IPPB therapy in relation to other therapies.

According to the Venegas background, as pressure is increased during inspiration, a net force is created that tends to separate the mask from the face, thereby decreasing contact pressure and potentiating air leaks. To maintain the seal, an elastic band, i.e., headgear, is used to hold the mask in place with a force sufficient to maintain the seal during inspiration. Typically, the sealing force is above capillary pressure and can therefore cause skin necrosis or facial sores due to the forces present at the interface between the patient and the mask or facial unit. Venegas, column 1, lines 20-34.

Venegas' purpose is to create a face mask for use with IPPB therapy, in which a sufficient seal with the patient's face is maintained during the positive pressure portion of the treatment cycle, but the mask does not exert an excessive, constant force which could result in skin necrosis and/or sores. (Emphasis added.) Column 1, lines 38-42.

Venegas accomplishes this goal by creating a mask with a piston assembly 14 that can move between the positions shown in Figs. 1 and 2, depending on whether positive pressure air is being delivered. Fig. 1 shows the relaxed position, while Fig. 2 shows the piston assembly 14 in an expanded position in which pressurized gas is delivered during the positive pressure portion of the respiratory cycle, during which time an air tight seal is created. However, "[w]hen pressure in the mask decreases, the contact force or the facial unit is likewise decreased and the seal is eliminated." (Emphasis added.) See the Venegas Abstract, last 3 lines.

The detailed description in Venegas is consistent with the Abstract. Venegas teaches that, in operation, the pressure before ventilation within the facial unit and the piston assembly is at ambient level and the contact pressure exerted by the facial unit 12 on the face is lower than capillary pressure. According to Venegas, during the positive pressure portion of the ventilation cycle, pressure in the piston chamber 36 and space 24 increases, causing the piston 14 to expand. The piston continues to expand to a point where straps 22 and support structure 16 cooperate to resist further expansion of the piston assembly. At this point, the region interior to the piston assembly 14 continues to expand until the facial unit is pressed against the patient's face with sufficient force to form an airtight seal. Following the positive pressure portion of the respiratory cycle, the pressure within the chamber 36 and space 24 returns to an ambient level and the contact pressure of the facial unit 12 to the patient's face is likewise reduced to its original level. See column 4, lines 35-55.

Thus, Venegas teaches a ventilatory cycle that includes a positive pressure portion in which a seal is present, and a non-positive pressure portion in which the seal is eliminated. Stated differently, before and after application of the positive pressure portion in IPPB therapy, the facial unit (mask) of Venegas is not pressed against the patient's face with sufficient force to form an airtight seal.

By contrast, claim 23 sets forth a mask for delivering breathable gas to a patient comprising, *inter alia*, a mask shell, a gusset portion, a cushion and a headgear. These components are structured and arranged relative to one another such that a component of contact force F_c of the cushion on the user's face is maintained in approximately constant proportion to the pressure of the supply of breathable gas, and a total force of the mask on the face F_m is maintained within a range of about 35-108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas to maintain the seal between the mask and the user's face over an operating pressure range of the mask, including a minimum operating pressure of the operating pressure range.

As described above, Venegas describes operating a ventilator in the expiratory phase of patient breathing in which the gas supplied is not sufficient to cause the mask to seal against the patient's face. During the lower or non-positive pressure portions of Venegas' ventilatory cycle, the seal is eliminated and therefore the component of contact force in Venegas is not in approximately constant proportion to the pressure of the supply of breathable gas, as recited in claims 23 and new claims 128 and 129.

Further, the total force of the mask on the face in Venegas would not be within a range of about 35 and 108 grams per gf/cm^2 pressure of the supply pressurized breathable gas to maintain the seal between the mask and the user's face over an operating pressure range of the mask,

including a minimum operating pressure of the operating pressure range, as recited in claim 23.

Venegas teaches eliminating the seal following the positive pressure portion of the respiratory cycle, such that the total force would not fall within the claimed range over an operating pressure range of the mask, including a minimum operating pressure of the operating pressure range.

Venegas also does not teach that the force F_c is maintained to at least equal a minimum sealing force for the seal ... at a minimum operating pressure of the mask, per new claim 127.

During the personal interview, and as reflected on the Interview Summary, the Examiners requested additional structure be added to claim 23 even though it was tentatively agreed, pending formal review, that Venegas does not teach the claimed subject matter. To address their concern, Applicants have two points. First, case law is clear that an apparatus or product claim can distinguish based on what it does, as opposed to claiming specific connections and assemblies, etc. See *In re Echerd*, 176 USPQ, 321, 322 (CCPA 1973) ("There is nothing intrinsically wrong in defining something by what it does rather than what it is. ... While the Patent Office may properly require proof that the functional limitations are not inherent characteristics of the prior art..., these potentially distinguishing features cannot simply be ignored.")

Second, claim 23 has been amended for clarity purposes only to recite that the mask shell, gusset portion cushion and headgear (structural components) are structured and arranged relative to one another so that the force F_c and the total force F_m are maintained as claimed.

Dependent claims 24-28 and 125 are allowable by virtue of their dependence on claim 23, and for their recitation of additional patentable subject matter. For example, Venegas does not teach or suggest that the force F_m is maintained within a range of about 40-88 (claim 24) or

about 50-88 (claim 25) grams per gf/cm^2 pressure of the supply of pressurized breathable gas, over an operating pressure range of the mask, including a minimum operating pressure.

Venegas does not teach that the operating pressure range is about $4\text{-}25 \text{ gf}/\text{cm}^2$, as recited in claim 26. Further, claim 27 recites that the expiration and contraction of the gusset portion permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face. The Office Action (page 4) indicates that the subject matter of claim 27 is "within the scope of the invention as seen in figures 1-4." As there is no express or implicit disclosure of such feature, the rejection under §102 is improper. Moreover, the Examiner has not made any statement that it would have been obvious to have provided Venegas with the feature recited in claim 27.

Venegas does not teach that the gusset portion includes a single gusset having a flexible side wall with a generally triangular cross section when not exposed to the supply of breathable gas that balloons to a generally rounded cross section when exposed to the supply of pressurized breathable gas. Venegas does not implicitly or expressly disclose this feature, thus making a rejection based on anticipation improper. Further, the Examiner has not provided any reasons why one of ordinary skill in the art would have provided Venegas with such structure.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 29-33 were rejected under 35 U.S.C. §103(a) over Venegas. This rejection is respectfully traversed.

At the outset, the Office Action recognizes that Venegas does not explicitly recite the subject matter of claim 29, for example. However, the Office Action again indicates that this feature is "within the scope of the invention," per column 3, lines 10-50. The Office Action has

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not established a *prima facie* case for obviousness. To do so, it is incumbent on the Patent Office to point out differences between the claims and the cited reference, which the Office Action has done, and to provide a reason why one of ordinary skill in the art would have modified Venegas to include those features. The Examiner has failed to make any assertion, based on any motivation, that it would have been obvious to include the features missing from Venegas.

In addition, Venegas does not teach or suggest that the mask is a CPAP mask. To make up for this deficiency, the Office Action asserts that it is "within the scope" of the invention to use the mask as a CPAP mask. However, in view of the express teachings in Venegas that it be used for IPPB treatment, it is incumbent on the Patent Office to establish a *prima facie* case that there is motivation to use the mask in CPAP treatment.

Reconsideration in view of the above arguments is respectfully requested.

New claims 130-135 are presented for consideration. As discussed during the interview, Venegas does not teach or suggest a mask frame, a cushion and a gusset portion with a gusset area constructed and arranged so that there is an approximately linear relationship between the force and the distance, as recited in claim 130. Claims 134-135 are means-plus-function claims added per the Examiners' helpful suggestion.

Attached is Form PTO-1449 citing US-2003-0089372-A1 (U.S. application Serial No. 10/322,578, filed December 19, 2002). This application is a continuation of the present application and has been allowed. A copy of the allowed claims is attached as well. The background excerpts mentioned on page 11 of the Remarks are also listed on the PTO-1449. It is not believed that any fee is necessary for the Patent Office to consider this information. However, if a fee is deemed necessary, the Patent Office is authorized to charge Deposit Account 14-1140 under Order No. 4398-169.

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In view of the above Remarks, Applicants respectfully submit that all of the claims are patentable and that the entire application is in condition for allowance.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____


Paul T. Bowen
Reg. No. 38,009

PTB:jls:jck

Attachments:

Textbook Excerpts
Form PTO-1449
Allowed Claims of USSN 10/322,578

1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

Allowed Claims
U.S. Application Serial No. 10/322,578,
a Continuation of U.S. Application Serial No. 09/885,445

1-124. Canceled.

125. A breathable gas mask arrangement, comprising:
a mask shell having a portion adapted to receive a supply of pressurized
breathable gas and a user side;
a gusset portion having a first side attached to the user side of the shell and having
a second side;
a cushion having a first portion attached to the second side of the gusset portion
and a second portion constructed and arranged to contact a user's face in use and provide
a seal between the mask arrangement and the user's face; and
headgear constructed and arranged to attach the mask shell to the user;
wherein the gusset portion is constructed and arranged such that it can expand and
contract to alter a distance between the mask shell and the cushion in use, the distance
being within a range of movement of the gusset portion that is greater than 0 mm and less
than 30 mm, and wherein an interior of the gusset portion is exposed to the supply of
pressurized breathable gas and has a projected area on the user's face A_g that is greater
than an area A_c of contact of the cushion with the user's face such that the supply of
pressurized breathable gas acting on the area A_g provides a component of a contact force
 F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.6 and less than
4.0.

126. The breathable gas mask arrangement according to claim 125, wherein the
gusset portion is structured to expand or contract from an initial position to a position that
is about 10-30 mm from the initial position.

127. The breathable gas mask arrangement according to claim 125, wherein the
gusset portion is structured to expand or contract from an initial position to a position that
is about 5-20 mm from the initial position.

128. The breathable gas mask arrangement according to claim 125, wherein the gusset portion is in the form of a piston that is axially slidably engaged with a cylinder portion of the shell.

129. The breathable gas mask arrangement according to claim 125, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

130. Canceled.

131. The breathable gas mask arrangement according to claim 125 wherein the ratio of A_g/A_c is in the range of 1.8-3.5.

132. A breathable gas mask arrangement, comprising:
a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;
a gusset portion having a first side attached to the user side of the shell and having a second side;
a cushion having a first portion attached to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and
headgear constructed and arranged to attach the mask shell to the user;

wherein the gusset portion includes an elastic sidewall having a spring constant that is at least partially determinative of a force applied to the patient's face through the second portion of the cushion.

133. The breathable gas mask arrangement according to claim 132, wherein the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion.

134. The breathable gas mask arrangement according to claim 133, wherein the distance is within a range of movement of the gusset portion that is greater than 0 mm and less than 30 mm.

135. The breathable gas mask arrangement according to claim 132, wherein an interior of the gusset portion is exposed to the supply of pressurized breathable gas and has a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.6 and less than 4.0.

136. The breathable gas mask arrangement according to claim 135, wherein the ratio of A_g/A_c is in the range of 1.8-3.5.

137. The breathable gas mask arrangement according to claim 132, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

Notice of References Cited		Application/Control No.	Applicant(s)/Patent Under Reexamination FRATER ET AL.	
		Examiner AARON J. LEWIS	Art Unit 3761	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-1,710,160	04-1929	Name not available	128/206.24
	B	US-2,625,155	01-1953	Name not available	128/206.24
	C	US-5,074,297	12-1991	Venegas, Jose G.	128/204.18
	D	US-5,349,949	09-1994	Schegerin, Robert	128/206.24
	E	US-5,540,223	07-1996	Starr et al.	128/205.25
	F	US-5,542,128	08-1996	Lomas, Christiane	2/173
	G	US-5,647,357	07-1997	Barnett et al.	128/206.24
	H	US-5,649,532	07-1997	Griffiths, Joseph Anthony	128/206.24
	I	US-5,657,752	08-1997	Landis et al.	128/207.13
	J	US-5,662,101	09-1997	Ogden et al.	128/205.25
	K	US-5,921,239	07-1999	McCall et al.	128/205.25
	L	US-5,937,851	08-1999	Serowski et al.	128/202.27
	M	US-6,192,886	02-2001	Rudolph, Kevin A.	128/207.13

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited		Application/Control No.	Applicant(s)/Patent Under Reexamination FRATER ET AL.	
		Examiner AARON J. LEWIS	Art Unit 3761	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,340,024	01-2002	Brookman et al.	128/201.25
	B	US-6,357,441	03-2002	Kwok et al.	128/207.13
	C	US-6,371,110	04-2002	Peterson et al.	128/202.27
	D	US-6,412,488	07-2002	Barnett et al.	128/207.13
	E	US-6,467,483	10-2002	Kopacko et al.	128/207.12
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
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	P					
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	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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IN THE CLAIMS:

Please cancel claim 1 without prejudice.

Please add the following new claim(s):

125. (New) A breathable gas mask arrangement, comprising:

a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

a gusset portion having a first side attached to the user side of the shell and having a second side;

a cushion having a first portion attached to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and

headgear constructed and arranged to attach the mask shell to the user;

wherein the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion in use, the distance being within a range of movement of the gusset portion that is greater than 0 mm and less than 30 mm.

126. (New) The breathable gas mask arrangement according to claim 125, wherein the gusset portion is structured to expand or contract from an initial position to a position that is about 10-30 mm from the initial position.

127. (New) The breathable gas mask arrangement according to claim 125, wherein the gusset portion is structured to expand or contract from an initial position to a position that is about 5-20 mm from the initial position.

128. (New) The breathable gas mask arrangement according to claim 125, wherein the gusset portion is in the form of a piston that is axially slidably engaged with a cylinder portion of the shell.

129. (New) The breathable gas mask arrangement according to claim 125, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that

balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

o 130. (New) The breathable gas mask arrangement according to claim 125, wherein an interior of the gusset portion is exposed to the supply of pressurized breathable gas and has a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.6 and less than 4.0.

o 131. The breathable gas mask arrangement according to claim 130 wherein the ratio of A_g/A_c is in the range of 1.8 – 3.5.

132. (New) A breathable gas mask arrangement, comprising:
a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;
a gusset portion having a first side attached to the user side of the shell and having a second side;
a cushion having a first portion attached to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and
headgear constructed and arranged to attach the mask shell to the user;
wherein the gusset portion includes an elastic sidewall having a spring constant that is at least partially determinative of a force applied to the patient's face through the second portion of the cushion.

133. (New) The breathable gas mask arrangement according to claim 132, wherein the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion.

134. (New) The breathable gas mask arrangement according to claim 133, wherein the distance is within a range of movement of the gusset portion that is greater than 0 mm and less than 30 mm.

11.10.10 and 11.10.11 to 1.421.616

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135. (New) The breathable gas mask arrangement according to claim 132, wherein an interior of the gusset portion is exposed to the supply of pressurized breathable gas and has a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.6 and less than 4.0.

136. (New) The breathable gas mask arrangement according to claim 135, wherein the ratio of A_g/A_c is in the range of 1.8 – 3.5.

137. (New) The breathable gas mask arrangement according to claim 132, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

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REMARKS

By this Preliminary Amendment, the specification has been amended to add the continuing data, claim 1 has been cancelled and new claims 125-137 have been added. Claims 125-137 are pending in the application.

Attached is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned "Version with markings to show changes made".

Prompt and favorable examination is earnestly solicited.

Respectfully submitted,

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Enclosure: Appendix

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APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The specification is changed as follows:

Page 1, line 1, please insert the following new paragraph

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Application No. 09/885,445, filed June 21, 2001, currently pending, U.S. Provisional Application No. 60/213,251, filed June 22, 2000, U.S. Provisional Application No. 60/219,618, filed July 21, 2000 and U.S. Provisional Application No. 60/293,992, filed May 30, 2001, the specifications and drawings of which are incorporated herein by reference.

IN THE CLAIMS:

Claim 1 is cancelled herein and claims 125-137 are newly presented.

End of Appendix